

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Inesa Benediktovna Kozlovskaya et al.

Group Art Unit: 3764

Examiner: Robert Franklin Long

Serial No.: 10/598,244

Filed: August 22, 2006

For: Suit for Forcedly Modifying a Human Posture and Producing an
Increased Load on a Locomotion Apparatus

Attorney Docket No.: ZAO 0101 PUSA

DECLARATION OF INESA BENEDIKTOVNA KOZLOVSKAYA
UNDER 37 C.F.R. § 1.132

Mail Stop AF
Commissioner for Patents
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Inesa Benediktovna Kozlovskaya, do hereby declare and state as follows:

1. I, Inesa Benediktovna Kozlovskaya, am M.D., PhD., D.Sc., Professor, graduated from the First Moscow Medical School in 1951; received a PhD degree in 1954 , a Doctor of Sciences degree in 1976; the title of Professor –in 1988.

- 1954-1959 - assistant professor at the Chair of Physiology of the I-st Moscow Medical School;
- 1959-1966 - senior researcher at the Institute of Higher Nervous Activity of Russian Academy of Sciences;

- 1966-1971 - guest-investigator at the Department of Behavioral Physiology of the Rockefeller University (N.Y.) and the Department of Physiology at the New York Medical College (USA);
- 1972-1977 - senior scientist of the Department of Motor Control at the Institute of Problems of Information Processing;
- 1977 up to now - Head of the Department of Sensory-motor Physiology and Countermeasures at the State Research Center of Russia-Institute of Biomedical Problems of Russian Academy of Sciences, Moscow.

In this capacity I am responsible for developing, ensuring and implementing all the Institute activities linked to studies of the effects of altered gravity on sensory-motor functions, including the International program of neurophysiological studies on monkeys and in space flights of Russian biosatellites, All-union program on Space Motion Sickness, International neurophysiological programs on board of Russian space Stations and others.

I am:

- Author more than 250 scientific publications, including 2 books and 4 monographs in the field of Motor Control, Sensory and Cerebellar Physiology, Gravitational Neurophysiology;
- Member of Board of Trustees of the International Academy of Aeronautics (IAA);
- Vice- President of the Research Group on Space and Underwater Neurology;
- Member of the International Commission on Gravitational Physiology of IUPS;
- Member of Moscow Physiological Association, of International Brain Research Organisation (IBRO);
- Member of American and European Society of Neuroscience;
- Member of the Editorial board of the International Journal of Gravitational Physiology and of Russian Journal "Sensory Systems".

I am:

- Corresponding Member of the Russian Academy of Sciences;
- Awarded by the title of Honoured Scientist of Russia /1996/;
- Award of Russian Government /1997/;
- State Award of Russia /2001/;

- Life Science Award of the International Academy of Aeronautics /1999/;
- Nelo Pace Award of Gravitational Committee.

The most recent publications relevant for this declaration:

1. Kozlovskaya I.B., Sayenko I.V., Miller T.F., Khusnutdinova D.R., Melnik K.A., Popov D.V., Vinogradova O.L., Yarmanova E.N., Tomilovskaya E.S. Erratum to: New approaches to countermeasures of the negative effects of micro-gravity in long-term space flights [Acta Astronautica 59,2006 13-19] //Acta Astronautica, 2007, V.60, N 8-9, pp. 783-789.
2. Kozlovskaya I.B., Sayenko I.V., Vinogradova O.L., Miller T.F., Khusnutdinova D.R., Melnik K.A., Yarmanova E.N. New approaches to countermeasures of the negative effects of microgravity in long-term space flights//Acta Astronautica 59, 2006, pp. 13-19.
3. Kozlovskaya I.B., Grigoriev A.I. "Russian system of countermeasures on the board of Internatuional Space Station: the first results" //Acta Astronautica, 2004, V.55, 233-237.
4. Bogomolov V.V., Grigoriev A.I., Kozlovskaya I.B. "The Russian experience in medical care and health maintainace of the ISS crews" //Acta Astronautica, 2007, V.60, 237-246.
5. Grigoriev A.I., Kozlovskaya I.B., Potapov A.N. "Goals of biomedical support to a Martian mission and possible approaches to achieving them" //Aviat. Space and Environ.Med, 2002, N4, 3079-3084.
6. Kozlovskaya I.B. Countermeasures for long-term space flights. Lessons learned from the Russian space program. J Gravit. Physiol. 9, 2002.

List of patents and patent publications in the USA:

1. US Patent 6,213,922 April 10, 2001 «Device for treatment of patients with disturbed posture and motor activity» Inventor: Afanasenko; Nikolai Ivanovich (Moscow, RU), Kozlovskaya; Inesa Benediktovna (Moscow, RU) (+8)
2. US 2007135278 June 14, 2007 «Suit for forcedly modifying a human posture and producing an increased load on a locomotion apparatus» Inventor: Grigoriev; Anatoly I. (RU), Kozlovskaya; Inesa B. (RU) (+2)
3. US 2008097263 April 24, 2008 «Device for mechanical stimulation of the foot support areas» Inventor: Grigoriev; Anatoly I. (RU), Kozlovskaya; Inesa B. (RU) (+3)

List of patents in Russia:

1. RU2197215 January 27, 2001 «A means of treatment of patients with pathologic neurological disorders in muscular tonus and pose regulation during diseases of central nervous, vestibular and locomotor systems» Inventor: Grigoriev A.I., Kozlovskaya I.B. (+3)
2. RU2221537, July 9, 2002 «A countermeasure means and a tool against ICP in children under 12 months with perinatal encephalopathy» Inventor: Grigoriev A.I., Kozlovskaya I.B. (+1)
3. RU2227048, September 11, 2002 «A means of rehabilitation and preservation of functional muscle abilities in humans under conditions of microgravitation and/or hypokinesia» Inventor: Grigoriev A.I., Kozlovskaya I.B. (+1)
4. Utility model RU44505 November 10, 2004 «Immersion tub» Inventor: Grigoriev A.I., Kozlovskaya I.B.
5. RU2295321 February 26, 2004 «Suit for forcedly modifying a human posture and producing an increased load on a locomotion apparatus» Inventor: Grigoriev A. I., Kozlovskaya; I. B. (+2)
6. RU2301622 December 2, 2005 «A computer preventive and correction means of unfavorable perceptive and sensomotor reactions» Inventor: Kornilova L. I., Kozlovskaya; I. B. (+3)
7. RU2307575 November 18, 2005 «A computer means of complex assessment of the state of vestibular function, intersensory interactions and a tracking eye function» Inventor: Kornilova L. I., Kozlovskaya; I. B. (+2)
8. RU2306960 May 11, 2005 «A means of enhancement of resistance to muscle exhaustion with preservation of maximal voluntary strength in humans» Inventor: Vinogradova O.L., Kozlovskaya; I. B. (+3)
9. RU2330640 April 12, 2005 «Device for mechanical stimulation of the foot support areas» Inventor: Grigoriev A.I., Kozlovskaya I. B. (+3)

2. Prior to the present invention, locomotion apparatus used loading elements which were only adjustable in discrete amounts, causing a discontinuous loading force change. Additionally, there was no way to control the loading force during the wearer's exercise and objective feedback during physical training for an individual was unavailable. The locomotion apparatus vests in the prior art were adjustable, however only across a small range.

3. In the final office action of January 22, 2009, the Examiner states that the loading member of Koscielny et al. 7,153,246 requires "a plurality of spaced apart adjustment nodes" (Page 3). The spaced apart adjustment nodes as well as the fixed attachment points on the suit provides the ability to apply a range of forces to the wearer in discrete amounts and only enables a discontinuous loading force change. When a pair of loading elements is used, e.g. one to each side of a shoe, the balance of these elements is important as it directly controls the amount of torque on the body part (e.g. foot) they are attached to and either placing them in exact balance to zero torque, or setting a precise torque is difficult given that the elements are only capable of gross adjustment and are connected to fixed attachment points, further limiting them.

The Examiner stated that Koscielny et al. 7,153,246 teaches that the "straps provide the desired neurological feedback during movement" (Page 11, Paragraph 4). The desired neurological feedback is subjective and not measured.

Additionally, the Examiner stated Senegal 2007/0083975 teaches a adjustment system "to accommodate users with different body sizes and shapes" by "adjustably threading" webbing. The adjustment features cause bunching of the material under the webbing when tightened, and can not comfortably fit a wide range of users while maintaining the loading attachment points in the correct locations.

4. A locomotion apparatus with the ability to apply forces across a continuous range has advantages over prior art locomotion apparatus with only the ability to apply forces across a range in discrete steps. When a pair of loading elements is used, e.g. one to each side of a shoe, the balance of these elements is important as it directly controls the amount of torsion and torque on the body part (e.g. foot) they are attached to. They need to be placed in either exact balance to a zero torque measurement, or be set to a precise force value to create a specific amount of torque. The continuous adjustment the loading elements are capable of in the present invention are critical in that given the differences in attachment positions between sides of a leg for example, the straps may need to be set to different lengths to obtain a zero torque balance or set to a precise length to obtain the torque required. The loading elements in the prior art are not capable of this continuous and fine adjustment.

A locomotion apparatus also has advantages over the prior art with the ability to use a dynamometric tape for objective measurement and adjustment during use, and with a pleat system for setting the transversal size to a standard size in a stepwise manner, corresponding for example to a standard clothes size, with the ability to finely tune the size of the fitting later. These advantages further include ability the dynamometric tape to coincide with the body for example during the bend over of the body not having any additional impact on the patient.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Inesa Benediktovna Kozlovskaya

Inesa Benediktovna Kozlovskaya

Date: 16.04.09